

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MEDTRONIC AVE, INC.,

Plaintiff,

vs.

BOSTON SCIENTIFIC CORP.,
SCIMED LIFE SYSTEMS, INC., BOSTON
SCIENTIFIC SCIMED, INC., and
MEDINOL, LTD.,

Defendants.

Civil Action No. 98-478-SLR

**ANSWER TO SECOND AMENDED COMPLAINT,
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendants Boston Scientific Corporation, Scimed Life Systems, Inc., Boston Scientific Scimed, Inc. and Medinol, Ltd. (collectively, "Defendants") hereby answer the Second Amended Complaint of Plaintiff Medtronic AVE, Inc. ("Medtronic AVE"). The allegations set forth below are based on Defendants' own knowledge as to their own activities, and upon information and belief as to the activities of others. The enumerated paragraphs correspond to the like-numbered paragraphs of the Second Amended Complaint. Accordingly, Defendants state and allege as follows:

ANSWER

1. Admitted, except Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation that Medtronic AVE is a "leading manufacturer of specialized stent delivery systems," and therefore deny the same.

2. Admitted.
3. Admitted, except Defendants deny that "SciMed regularly does or solicits business in the State of Delaware, engages in a persistent course of conduct in the State of Delaware, and/or derives substantial revenue from services or things used in the State of Delaware."
4. Admitted, except Defendants deny that "Boston Scientific SciMed regularly does or solicits business in the State of Delaware, engages in a persistent course of conduct in the State of Delaware, and/or derives substantial revenue from services or things used in the State of Delaware."
5. Admitted, except Defendants deny that "Medinol engages in a persistent course of conduct in the State of Delaware and/or derives substantial revenue from services or things used in the State of Delaware," and further deny that "Medinol has granted Boston Scientific an exclusive license to market and distribute Medinol stents in the United States including Delaware."
6. Admitted.
7. Admitted.
8. Admitted.
9. Admitted.
10. Defendants deny that U.S. Patent No. 5,292,331 ("the '331 Patent") was "duly and legally issued," but otherwise admit the allegations.
11. Defendants deny that U.S. Patent No. 5,674,278 ("the '278 Patent") was "duly and legally issued," but otherwise admit the allegations.

12. Defendants deny that U.S. Patent No. 5,879,382 ("the '382 Patent") was "duly and legally issued," but otherwise admit the allegations.

13. Denied.

14. Defendants respectively deny or admit the allegations in paragraphs 1-12 of the Second Amended Complaint as specified in paragraphs 1-12 above.

15. Denied.

16. Denied.

17. Denied, except Defendants Boston Scientific Corp., Scimed Life Systems, Inc. and Boston Scientific Scimed, Inc. (collectively, "BSC/Scimed") admit that they have been aware of the '331 and '278 patents.

18. Denied.

19. Denied, except Defendants BSC/Scimed admit that they have been aware of the '331 and '278 patents.

20. Denied.

21. Denied.

22. Denied.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The '331, '278 and '382 patents are invalid for failure to comply with one or more of the requirements of the United States Patent Statute, codified at Title 35 of the United States Code, including but not limited to sections 101, 102, 103, 111, 112 and 116 thereof.

Second Affirmative Defense

By reason of the state of the prior art and proceedings in the U.S. Patent and Trademark Office during prosecution of the applications which led to the issuance of the '331, '278 and '382 patents, including amendments to the claims and arguments and other statements made during prosecution by or on behalf of the patentee, Medtronic AVE is estopped from asserting that Defendants have infringed or are infringing the '331, '278 and '382 patents.

Third Affirmative Defense

The '278 and '382 patents are invalid under the doctrine of double patenting.

Fourth Affirmative Defense

On information and belief, Medtronic AVE is barred, in whole or in part, from recovery for any alleged infringement by Defendants because of Medtronic AVE's failure to comply with the requirements of 35 U.S.C. § 287.

Fifth Affirmative Defense

Defendants have not engaged in activities that constitute a direct or contributory infringement of any valid and enforceable claim of the '331, '278 or '382 patents, do not now engage in such activities, and have no plans to do so in the future. Further, Defendants have not engaged in activities that constitute an inducement of others to infringe the '331, '278 or '382 patents, do not now engage in such activities, and have no plans to do so in the future.

Sixth Affirmative Defense

On information and belief, Medtronic AVE is not the rightful owner of the '331, '278 or '382 patents, and therefore lacks standing to maintain this action for patent infringement.

Seventh Affirmative Defense

On information and belief, the '331, '278 and '382 patents are unenforceable due to inequitable conduct during prosecution of the applications that led to the issuance of the patents, including but not necessarily limited to the intentional failure to identify one or more joint inventors of the subject matter claimed in the patents. On information and belief, this fraudulent procurement is the subject matter of allegations in at least two civil actions: *Azam Anwar, M.D. et al. v. Arterial Vascular Eng'g et al.*, No. 96-05323 (Dallas County, Texas) and *Rodolfo Di Massa, M.D. et al. v. Simon Stertz et al.*, No. 222363 (Sonoma County, California).

Request for Relief as to Medtronic AVE's Second Amended Complaint

WHEREFORE, Defendants request that the Court:

- (a) Deny Medtronic AVE any and all relief for any claim in the Second Amended Complaint;
- (b) Enter judgment in favor of Defendants and against Medtronic AVE on each purported claim in the Second Amended Complaint, dismissing each such claim with prejudice;
- (c) Award Defendants their costs and attorneys' fees incurred in defending against Medtronic AVE's claims in this action; and

(d) Grant Defendants such other and further relief as the Court deems just and proper.

COUNTERCLAIMS

Counterclaim Plaintiffs Boston Scientific Corporation, Scimed Life Systems, Inc., Boston Scientific Scimed, Inc. and Medinol, Ltd. (collectively, "Counterclaim Plaintiffs"), for their Counterclaims against Counterclaim Defendant Medtronic AVE, Inc. ("Medtronic AVE"), allege and state as follows:

Count I

DECLARATORY JUDGMENT OF INVALIDITY, UNENFORCEABILITY AND NONINFRINGEMENT

1. This is a civil action for a declaratory judgment that U.S. Patent No. 5,292,331, U.S. Patent No. 5,674,278, and U.S. Patent No. 5,879,382 (collectively, the "Patents-in-Suit") are invalid, unenforceable and not infringed by Counterclaim Plaintiffs, whether directly, contributorily, or by inducing infringement.
2. This Court has subject matter jurisdiction over this counterclaim under 28 U.S.C. §§ 1331 and 1338, as well as pursuant to the Court's supplemental jurisdiction under 28 U.S.C. § 1367.
3. Medtronic AVE claims to be the owner of the Patents-in-Suit, and to possess the right to sue and recover damages for infringement thereof.
4. Arterial Vascular Engineering, Inc. ("AVE") originally filed this suit against Boston Scientific Corporation and Scimed Life Systems, Inc. on August 13, 1998, alleging that products sold by them infringe the Patents-in-Suit. AVE then amended its complaint on March 11, 1999 to substitute Medtronic AVE as the nominal plaintiff.

Medtronic AVE then filed its Second Amended Complaint to add Boston Scientific Scimed, Inc. and Medinol, Ltd. as defendants, as well as to add the '382 Patent.

5. As a result of the aforementioned suit, there is an actual and justiciable controversy between the parties concerning the validity, enforceability and infringement of the Patents-in-Suit sufficient to meet the requirements of the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. Counterclaim Plaintiffs have not engaged in activities that constitute direct or contributory infringement of any valid and enforceable claim of the Patents-in-Suit, do not now engage in such activities, and have no plans to do so in the future.

7. Counterclaim Plaintiffs have not engaged in activities that constitute inducement of others to infringe the Patents-in-Suit, do not now engage in such activities, and have no plans to do so in the future.

8. The Patents-in-Suit are invalid for failure to comply with one or more of the requirements of the United States Patent Statute, codified at Title 35 of the United States Code, including but not limited to sections 101, 102, 103, 111, 112 and 116 thereof.

9. U.S. Patent No. 5,674,278 and U.S. Patent No. 5,879,382 are invalid under the doctrine of double patenting.

10. On information and belief, the Patents-in-Suit are unenforceable due to inequitable conduct during prosecution of the applications that led to the issuance of the patents, including but not necessarily limited to the intentional and fraudulent failure to identify one or more joint inventors of the subject matter claimed in the patents. On information and belief, this fraudulent procurement is the subject matter of allegations in

at least two civil actions: *Azam Anwar, M.D. et al. v. Arterial Vascular Eng'g et al.*, No. 96-05323 (Dallas County, Texas) and *Rodolfo Di Massa, M.D. et al. v. Simon Stertz et al.*, No. 222363 (Sonoma County, California).

Count II

ANTITRUST VIOLATION

11. This is a civil action for violation of Section 2 of the Sherman Act, codified at Title 15, Section 2 of the United States Code.

12. This court has subject matter jurisdiction over this counterclaim under 28 U.S.C. §§ 1331, 1337(a) and 15 U.S.C. §§ 15 and 26, as well as pursuant to the Court's supplemental jurisdiction under 28 U.S.C. § 1367.

13. A relevant market exists in the United States for the manufacture and sale of stents for implantation in coronary arteries (hereinafter, the "Coronary Stent Market"). Counterclaim Plaintiffs compete with Medtronic AVE and a small number of other competitors in this market.

14. On information and belief, Medtronic AVE has substantial market power in the Coronary Stent Market, holding a market share of approximately 15-20%.

15. On information and belief, the patents-in-suit were obtained by Arterial Vascular Engineering, Inc. ("AVE"), the predecessor-in-interest of Medtronic AVE, as a result of fraud on the U.S. Patent and Trademark Office, including but not necessarily limited to the intentional and fraudulent failure to identify one or more joint inventors of the subject matter claimed in the patents. On information and belief, this fraudulent procurement is the subject matter of allegations in at least two civil actions: *Azam Anwar, M.D. et al. v. Arterial Vascular Eng'g et al.*, No. 96-05323 (Dallas County, Texas) and

Rodolfo Di Massa, M.D. et al v. Simon Stertzer et al., No. 222363 (Sonoma County, California).

16. AVE was aware of the fraudulent procurement of the Patents-in-Suit at the time it filed the present action for patent infringement against Boston Scientific Corp. and Scimed Life Systems, Inc. In addition, Medtronic AVE was aware, or should have been aware, of AVE's fraudulent procurement of the Patents-in-Suit at least as of the time Medtronic AVE became the nominal plaintiff in this action.

17. On information and belief, AVE fraudulently procured the Patents-in-Suit from Endovascular Support Systems, Inc. ("ESS"), the original owner of the subject matter claimed therein. On information and belief, this fraudulent procurement is the subject matter of allegations in the above-cited civil action brought by Dr. Azam Anwar in Texas.

18. AVE was aware of the fraudulent procurement of the Patents-in-Suit from ESS at the time it filed the present action for patent infringement against Boston Scientific Corp. and Scimed Life Systems, Inc. In addition, Medtronic AVE was aware, or should have been aware, of AVE's fraudulent procurement of the Patents-in-Suit from ESS at least as of the time Medtronic AVE became the nominal plaintiff in this action.

19. Despite their respective knowledge of the fraudulent procurement of the Patents-in-Suit, AVE filed this patent infringement suit, and Medtronic AVE maintained the suit, with the express anticompetitive purpose of attempting to monopolize the Coronary Stent Market by forcing Counterclaim Plaintiffs' NIR® stent products out of the market. On information and belief, Medtronic AVE is asserting these same

fraudulently-procured patents against other competitors in the Coronary Stent Market in furtherance of this effort to monopolize that market.

20. If permitted to continue its enforcement of patent rights obtained through knowing and willful fraud, it is likely that Medtronic AVE will succeed in its unlawful and anticompetitive attempts to force Counterclaim Plaintiffs' NIR® stent products and other competitive products out of the Coronary Stent Market.

21. Because of Medtronic AVE's violation of Section 2 of the Sherman Act, Counterclaim Plaintiffs have and will continue to sustain injury to their business and property for, *inter alia*, losses in sales of coronary stents, costs of defending against meritless claims of patent infringement, and costs inherent in the disruption of Counterclaim Plaintiffs' business. This injury will continue unless Medtronic AVE is prevented from continuing this illegal activity.

22. Unless Medtronic AVE is enjoined from continuing its anticompetitive conduct, Counterclaim Plaintiffs, as well as other competitors in the Coronary Stent Market and consumers of coronary stents, will suffer irreparable harm for which there is no adequate remedy at law.

Request for Relief as to BSC/Medinol's Counterclaims

WHEREFORE, Counterclaim Plaintiffs request that the Court:

- (a) Enter judgment declaring that Counterclaim Plaintiffs have not directly infringed, contributorily infringed, or induced infringement of any valid and enforceable claim of the '331, '278 and '382 patents;

(b) Enter judgment declaring that the '331, '278 and '382 patents are invalid and void for failure to comply with one or more of the requirements of the United States Patent Statute, codified at Title 35, United States Code, including but not limited to sections 101, 102, 103, 111, 112 and 116 thereof;

(c) Permanently enjoin Medtronic AVE and its officers, agents, employees, representatives, counsel and all persons in active concert or participation with any of them, directly or indirectly, from threatening or charging infringement of, or instituting any action for infringement of the '331, '278 or '382 patents against Counterclaim Plaintiffs, their suppliers, customers or any distributor or user of their products;

(d) Enter judgment declaring that Medtronic AVE has violated Section 2 of the Sherman Act, 15 U.S.C. § 2;

(e) Permanently enjoin Medtronic AVE and its officers, agents, employees, representatives, counsel and all persons in active concert or participation with any of them, directly or indirectly, from continuing Medtronic AVE's violation of the Sherman Act, as authorized by Section 16 of the Clayton Act, 15 U.S.C. § 26;

(f) Award Counterclaim Plaintiffs treble the damages that they have suffered as a result of Medtronic AVE's violation of the Sherman Act, as authorized by Section 4 of the Clayton Act, 15 U.S.C. § 15;

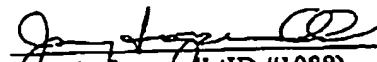
(g) Award Counterclaim Plaintiffs their costs and attorneys' fees pursuant to 35 U.S.C. § 285 and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26; and

(h) Grant Counterclaim Plaintiffs such other and further relief as the Court
deems just and proper.

Respectfully submitted,

Dated: July 13, 2000

By:


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Certificate of Service

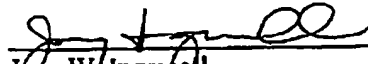
I, Josy W. Ingersoll, hereby certify that copies of the foregoing Answer to Second Amended Complaint, Affirmative Defenses and Counterclaims were caused to be served on July 13, 2000 upon the following counsel of record in the manner indicated:

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